

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

DOUGLAS KAYE

Plaintiff

VS.

SYNTHE (U.S.A.)

Defendant

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CAUSE NO. 4:05-CV-02809

**SYNTHE'S OBJECTIONS AND RESPONSE TO THE MAGISTRATE'S
MEMORANDUM AND RECOMMENDATION**

TO THE HONORABLE UNITED STATES DISTRICT JUDGE:

Pursuant to Rule 72 of the Federal Rules of Civil Procedure, Defendant Synthes (U.S.A.) responds and objects to portions of the Memorandum and Recommendation signed by the Honorable Stephen Wm Smith on May 11, 2007.¹ Instead of entering the Magistrate's recommendations (to grant Synthes motion to strike and to grant only portions of Synthes' motions for summary judgment while allowing plaintiff's manufacturing defect claim to proceed to trial), Synthes urges the Court, after a *de novo* review, to grant both Synthes' motions to strike and for summary judgment in their entirety.

I.

Overview

This product liability case involves a specialized prescriptive medical device surgically implanted along a broken bone with the goal of fixating and stabilizing the bone during the healing

¹ References to Judge Smith's Memorandum and Recommendation (abbreviated as "Mem.") are by page number. References to Dr. Sitter's deposition is by name and page number. References to the affidavits of Dr. Lemmons and Dr. Labbe are to the affidavit followed by a reference to the appropriate numbered paragraph.

process. Simply put, the subject product is a bone fixation plate. The particular plate at issue in this case was one of three different plates used in the numerous surgical efforts to fix Plaintiff's clavicle which was broken in a skiing accident. Despite the specialized nature of the subject product, Plaintiff has offered no expert testimony in support of his claims that the plate was somehow defective, and neither the plate nor any of the pertinent x-rays can now be located.

Based upon the motions and evidence before him, Judge Stephen Wm Smith issued his Memorandum and Recommendation on May 11, 2007, recommending that Plaintiff's experts be struck (Mem. at 3) and that trial proceed only on Plaintiff's manufacturing defect claim (Mem. at 13). Judge Smith recommended that Plaintiff's design, marketing and warranty claims be dismissed (Mem. at 7 & 9) and that the court exercise its own discretion on whether the jury should be instructed on evidence spoliation and adverse inferences which can be drawn therefrom (Mem. at 12-13). Synthes objects to Judge Smith's Memorandum and Recommendation to the extent and based upon the reasons set out below.

II.

Synthes' Specific Objections

Pursuant to Rule 72 of the Federal Rules of Civil Procedure, Synthes specifically objects to the Magistrate's conclusions that:

Dr. Sitter's testimony is sufficient to create a fact issue on plaintiff's manufacturing defect claim (Mem. at 12);

a manufacturing defect could "certainly" cause a plate to break (Mem. at 10);

the common knowledge defense does not apply to this case (Mem. at 9);

Dr. Labbe's report does not purport to give an opinion as to the existence of a manufacturing defect (Mem. at 11);

Dr. Labbe's affidavit is not sufficient evidence that a manufacturing defect did not cause the plate to break in this case (Mem. at 10);

Synthes's experts "are no more competent than Kaye's² were to offer a competent opinion as to the failure mechanism of the subject plate without examining the plate itself" (Mem. at 11);

Dr. Lemmons does not address the significance of the break occurring laterally to the bone fracture (Mem. at 11);

Dr. Lemmons' opinion that the particular plate at issue in this case was, in all probability, not defectively manufactured did not rule out the possibility that the plate in this case broke because it was defective (Mem. at 11); and,

a material fact issue exists as to whether the broken plate was returned to Synthes (Mem. at 12).

These conclusions, and any implications subsumed therein, are plainly erroneous, without moment, or contrary to law. Additionally, Synthes specifically objects that the Magistrate's recommendations are silent as to Plaintiff's burden to come forward with some evidence of causation as a prerequisite to trial.

² Included in this objection is Synthes' objection to the Magistrate's apparent implication that Dr. Sitter was designated or is in any way competent to testify on manufacturing issues. He was not and is not.

III.

Argument in Support of Objections

The gist of Synthes' objections is that there is no competent evidence – circumstantial or otherwise – nor any lawful basis to infer evidence in support of Plaintiff's manufacturing defect claim. Without competent evidence, any trial of this issue would be at best a waste and at worst an injustice.

A. No Evidence Exists on which to Proceed to Trial on any Manufacturing Defect Claim.

Unless Plaintiff brings forward some evidence that the plate deviated, in terms of construction or quality, from the specifications or planned output for the plate in so significant a manner as to render the plate unreasonably dangerous, there is no legal basis to proceed to trial on Plaintiff's manufacturing defect claim. *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004). Further, even if such a deviation from the specifications or planned output were to be identified in the plate, Plaintiff must also establish that the plate was defective when it left the hands of the manufacturer and that the defect was a producing cause of Plaintiff's injuries. *See American Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420 (Tex. 1996); *Walker v. Thommason Lumber Co.*, 203 S.W.3d 470, 473 (Tex. App.–Houston[14th Dist.] 2006, no pet.).

Because the subject product has been lost, there cannot be the physical examination and comparison with the design and manufacturing specifications necessary to definitively determine if a manufacturing defect exists. As a result, Plaintiff admits that he can offer no direct evidence of a manufacturing defect. However, Texas law allows competent circumstantial evidence to raise a genuine issue of the existence of a manufacturing defect. *Ford v. Ridgway*, 135 S.W.3d at 601. The key, however, to raising a genuine issue of fact with circumstantial evidence is that "the evidence must transcend mere suspicion. Evidence that is so slight as to make any inference a guess is in legal

effect no evidence.” *Id.* (citing *Lozano v. Lozano*, 52 S.W.3d 141, 148 (Tex. 2001)). Further, evidence – including circumstantial evidence – must be of a material fact. *See Ford v. Ridgeway*, 135 S.W.3d at 601-02.

Plaintiff argues that Dr. Sitter’s testimony provides circumstantial evidence of a manufacturing defect, and Judge Smith seems to have simply accepted Plaintiff’s naked assertion that Dr. Sitter’s surprise at the precise location of the plate breakage constitutes circumstantial evidence of the existence of a manufacturing defect. It does not. Not only does Dr. Sitter offer no opinions or observations which would do anything other than negate a manufacturing defect,³ Dr. Sitter is wholly unable and unwilling to opine on why the plate broke. What Dr. Sitter offers is “surprise” that the plate broke through the nearest screwhole lateral to the bone fracture, instead of through the solid cross-sectional area of the plate directly abutting the broken bone. The legal effect, however, of Dr. Sitter’s surprise is nothing. In short, Dr. Sitter’s surprise provides no evidence of a material fact because it does not even rise to the level of suspicion of a manufacturing defect, much less transcend it.

- 1. Dr. Sitter’s subjective surprise that the plate broke through a screwhole does not rise to the level of evidence upon which the fact-finder can infer that a manufacturing defect caused the plate to break.**

In a proper analysis of Plaintiff’s manufacturing defect claim, the material question is not whether the plate broke (or even where the plate broke). The material question is why the plate broke – whether it broke because of a manufacturing defect. Thus, Dr. Sitter’s surprise as to where the plate broke can only be competent circumstantial evidence allowing this case to proceed to trial if it is legally sufficient to support an inference that the plate broke where it did because it was

³ Dr. Sitter testified that he visually inspected the plate during the implantation surgery and saw no visible manufacturing defect. Sitter Dep. 36-37.

defective (in its manufacture) at the time it left Synthes' hands. *See Ford v. Ridgway*, 135 S.W.3d at 602. It does not.

Dr. Sitter does not express surprise that the plate broke, nor is he able to draw any conclusion or offer any opinion based upon the location of the plate breakage. ("Where this [plate] broke didn't necessarily fit the usual patterns." Sitter Dep. 59) Instead, Dr. Sitter stated that he personally could not explain the location of the plate breakage. ("I don't have a good explanation as to why it broke there." Sitter Dep. 63.) He did **not** testify that the location of plate breakage indicated a product defect. He did not even link the plate breakage to the possibility of a manufacturing defect. Moreover, the specific testimony relied upon by Plaintiff as circumstantial evidence of a defect is the essence of speculation. ("I can't explain it. I don't know why it broke where it did. I don't -- from my teaching and courses and what I know about these plates and that sort of thing, I don't have, at this point, a good explanation as to why it broke where it did. I didn't expect it. Is it explainable? Probably, but I'm not the engineer that designed them, and, you know, I really don't know." Sitter Dep. 115.)

The fact that Dr. Sitter did not want to guess as to why the plate broke ("It broke, and I'm not here to guess as to why." Sitter Dep. 57.) and never once opined that a manufacturing defect was even a possible cause of the plate breakage is entirely in keeping with the limited area of his expertise. Dr. Sitter repeatedly stated that he was not an engineer or a designer of such plates. Sitter Dep. 114-115. He also repeatedly stated that he had no opinion and could not explain why the plate broke. Sitter Dep. 114-115. Dr. Sitter is, by virtue of his training and experience in choosing orthopedic fixation plates, an expert in the field of selecting, implanting, and removing such plates. Dr. Sitter is not, however, an expert -- designated or otherwise -- in the manufacture of such plates. To then use a non-expert's "surprise" at where the plate broke as the sole basis to infer the existence

of a manufacturing defect—especially when that same witness specifically testifies that why the plate broke where it did is probably explainable by an engineer who designs such plates, is improper and contrary to law. Accordingly, the Magistrate’s conclusion that Dr. Sitter’s testimony is sufficient to create a fact issue on plaintiff’s manufacturing defect claim should not be adopted by this Court. Instead, Synthes’ motion for summary judgment should be granted in its entirety.

2. The bare fact that the plate broke, even if Dr. Sitter was surprised at the location of the break, is not circumstantial evidence of a manufacturing defect.

“Texas law does not generally recognize a product failure standing alone as proof of a product defect.” *Cooper Tire & Rubber Co. v. Mendez*, 204 S.W.3d 797, 807 (Tex. 2006). Allowing a witness’ surprise as to the location of a plate’s breakage to support an inference of a manufacturing defect is no more proper than allowing the bare fact that the plate broke to support such an inference.

Every expert, including Dr. Sitter, has testified that the fact that the plate broke is not evidence of any defect in the plate.⁴ The fact of the matter is that bone fixation plates can and do break in the absence of any product defect. Sitter Dep. 14-15; Labbe Aff. 7; Lemmons Aff. 4 & 6. This fact is considered “common knowledge” among the surgeons who choose and use internal fixation devices,⁵ and is otherwise recognized in the medical literature and taught to orthopedic

⁴ Sitter Dep. 14-15; Labbe Aff. 7; Lemmons Aff. 4.

⁵ While it is true, as Judge Smith stated (Mem. At 9), a common knowledge defense does not generally apply to a manufacturing defect claim because a user does not anticipate a manufacturing defect, it does not vitiate the probative value of the “common knowledge” of the community of surgeons who choose and use these plates as to the fact that when these plates break (already an uncommon occurrence) it is rarely due to a manufacturing defect. To decline consideration of this common knowledge negating the likelihood of a manufacturing defect while allowing for a chain of inferences based upon mere speculation and possibilities (particularly those asserted by counsel, not by any witness or expert) is contrary to both law and reason.

Additionally, a common knowledge defense has been argued by Synthes in connection with Plaintiff’s marketing defect claims which have been recommended for dismissal. (Mem. At 7.) In that context, the law provides that there is no duty to warn of dangers that are common knowledge to the users – in this case the implanting surgeons. See *Coleman v. Cintas Sales Corp.*, 100 S.W.3d 384, 386

surgeons early in their residencies. Sitter Dep. 14-15 & Lemmons Aff. 4 & 6. Not one witness, including Dr. Sitter, testified that even a possible cause of the plate breaking where it did (or even that it did) was a manufacturing defect. To the point, neither, Dr. Sitter nor any other witness even suggested the possibility of a manufacturing defect as a cause for the plate to break. As a result, there is no proper legal basis for the Magistrate to conclude that “a manufacturing defect could certainly cause [the] plate to break,” and to, thus, ignore the competent uncontroverted evidence (from Sitter, Labbe’ and Lemmons) that plates break in the absence of any defect. No one with any competent expert training or knowledge testified that the place of the break more likely than not, evidenced a manufacturing defect.

3. Drs. Labbe’s and Lemmons’ provide competent uncontroverted evidence negating the existence of a manufacturing defect.

While not Synthes’ burden or otherwise required to entitle Synthes to summary judgment, Dr. Labbe’s report provides evidence specifically negating the existence of a manufacturing defect. (“I saw no indication that the Synthes plate was defective” and “[t]he fact of the matter is that plates can, and occasionally do, break without being in any way defective. I believe that is what happened in this case.” Labbe Aff. 7 & 8.) This evidence was clear and competent. Most importantly, this evidence was uncontroverted. As a result, Judge Smith’s conclusion that Dr. Labbe’s affidavit is not sufficient evidence that a manufacturing defect did not cause the plate to break is contrary to law. *See Little v. Liquid Air. Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc) (“We resolve factual controversies [for purposes of summary judgment] in favor of the nonmoving party, but only when there is an actual controversy. That is, when both parties have submitted evidence of contradictory

(Tex. App.—San Antonio 2002, pet. denied).

facts. We do not, however, in the absence of any proof, assume that the nonmoving party could or would prove the necessary facts.”)

Similarly, Dr. Lemmons does address the significance and commonality of where the plate broke; *i.e.*, through a screw hole as opposed to through the entire metallic cross-sectional area of the plate. Lemmons Aff. 5. Dr. Lemmons testifies that the plate broke at this location precisely because of the screw hole, and that it would not break directly at the site of the bone fracture because it would then have to break through the entire “planar cross sectional area of the plate.” Lemmons Aff. 5. It is based upon his 36 years of experience with orthopedic biomaterials and biomechanics as well as his personal experience with laboratory and clinical retrieval studies of broken bone fixation plates that Dr. Lemmons’ was able to opine that the plate was, “in all probability, not defectively manufactured.” This opinion has not been contradicted. As a result, this clear, competent, uncontroverted evidence negating a manufacturing defect should trump any mere speculation that the plate broke because it was defective in its manufacture. Judge Smith’s declaration that Dr. Lemmons’ testimony “does not rule out the possibility that the plate in this case broke because it was defective” (Mem. at 11) shifts the burden to Synthes without regard to any guiding legal principles. The Magistrate’s declaration apparently requires Synthes, which bears no measure of the burden of proof, to disprove every conceivable possibility of defect (not simply those raised by competent evidence) before granting summary judgment. Such a declaration not only improperly shifts the burden, but requires that Synthes bear a greater burden of proof than the Plaintiff would have at trial.

Allowing that the possibility exists for the existence of a manufacturing defect is not the same thing as stating that it broke because of a manufacturing defect. Nor is such an allowance proper evidence of a manufacturing defect. Certainly, such a statement does not present more than a scintilla of evidence that a manufacturing defect existed at the time the plate left Synthes and that

such defect caused this plate to break when and where it did. Judge Smith's findings related to "possibilities" do not rise to the level of evidence and should not be the basis for this Court's judgment. See *Volkswagen of America, Inc. v. Ramirez*, 159 S.W.3d 897, 910 (Tex. 2004) (citing *Schaefer v. Texas Employers' Insurance Assn.*, 612 S.W.2d 199, 204 (Tex. 1980) in holding that evidence based on "mere possibility, speculation and surmise" is legally insufficient). This should be particularly true in this case where to find for the Plaintiff, the Court would have to link a chain of legally insupportable inferences to even get to the possibility of a manufacturing defect causing Plaintiff injury.

In sum, Plaintiff has not and cannot prove his manufacturing defect theory. There is and there can be no evidence with which to go forward to trial. Further the difficulty in proving the elements of a cause of action does not relieve Plaintiff of his obligation to do so. *Wal-Mart Stores, Inc. v. Gonzales*, 968 S.W.2d 934, 937 (Tex. 1998); *Schaefer v. Texas Employers' Ins. Ass'n*, 612 S.W.2d 199, 205 (Tex. 1980). "[T]he harsh reality is that if the plaintiff cannot prove facts to support [its] cause of action, there is simply no recovery. This is not only in slip and fall cases, but in all cases." *Wal-mart Stores, Inc. v. Gonzalez*, 968 S.W.2d at 937.

In an apparent effort to avoid the harsh realities of Plaintiff's failure to meet his burden of bringing forth evidence, Judge Smith has expressed his hesitation to preclude Plaintiff from his day in court where "his inability to present evidence may be Synthes' fault and not his own." (Mem. at 12, emphasis added). However, in order for Plaintiff to be legally entitled to his day in court, there must be some evidence to support the "may." In other words, there must be sufficient evidence of spoliation on the part of Synthes such that it is reasonable to infer that the plate was in fact defectively manufactured. There is not.

B. Not Only is there No Legal Basis for Plaintiff's Spoliation Allegation, but also this Allegation does not Meet Fifth Circuit Requirements

Plaintiff presents his spoliation argument as if a question of whether the plate was returned to Synthes gives rise to an inference of spoliation and, thus, relieves his burden of bringing forth evidence to support his cause of action. It does not. Were this court to adopt the Magistrate's finding that a question of fact exists as to whether the plate was returned to Synthes, such a finding would be entirely without moment. The question of whether the plate was returned to Synthes (a question which is vigorously denied by Synthes) is simply not material. Indeed, even if the return of the plate to Synthes was conclusively proven, such proof would not be legally sufficient under Fifth Circuit precedent to support a spoliation sanction. *See King v. Ill. Central Railroad*, No 02-60587 (5th Cir. July 21, 2003) (citing *United States v. Wise*, 221 F.3d 140, 156 (5th Cir. 2000 and affirming summary judgment and holding that it is improper to entertain a spoliation claim and apply an adverse inference of liability – *even in the face of the actual intentional destruction of potential evidence by a defendant after suit had been filed* – without clear evidence of actual “bad conduct” on the part of the defendant).

Here, there is absolutely no evidence that Synthes engaged in any bad conduct causing the loss or the destruction of the plate. Indeed, Plaintiff has brought forth only a hint of evidence that the plate was even sent to Synthes, no evidence that it was received by Synthes, no evidence that it was destroyed by anyone, and absolutely no evidence that Synthes or its counsel acted in bad faith. Without even the merest whiff of evidence of spoliation by Synthes, there is absolutely no legal basis to infer that, because the subject plate is now lost, it must somehow have been defective in its manufacture. *See San Antonio Credit Union v. O'Connor*, 115 S.W.3d 82, 92 (Tex. App.–San

Antonio 2003, pet. denied)(“vital facts may not be proven by unreasonable inferences or by piling inference upon inference. . . a chain of inferences can only be stretched so far before it snaps”).

Without an inference that a manufacturing defect existed and caused Plaintiff damage, Plaintiff fails in his obligation to bring forth some evidence which creates a genuine issue of material fact. Thus, summary judgement is mandated on Plaintiff’s manufacturing defect claims. *See, e.g., Krim v. BancTexas Group, Inc.*, 989 F.2d 1435, 1449 (5th Cir. 1993)(summary judgment is appropriate if “nonmoving party rests merely upon conclusory allegations, improbable inferences, and unsupported speculation”).

C. There is No Causal Link Between the Subject Plate and any of Plaintiff’s Damages.

Synthes’ motion for summary judgment specifically addresses and provides evidence which negates any causal link between any alleged defect in the subject plate and any damages suffered by Plaintiff.⁶ Plaintiff failed to even respond to Synthes’ motion and evidence negating causation. Without evidence of causation, Plaintiff’s claims fail and should be dismissed. *See Mosley v. Excel Corp.*, 109 F.3d 1006, 1009 (5th Cir. 1997)(holding that the requisite proof of causation requires not only that a plaintiff prove that the product defect was a producing cause of his injuries, but also that it be proven with something more than conjecture or guess)

D. Some Magistrate Findings are Without Objection by Synthes

Based upon the motions and evidence before him, Judge Stephen Wm Smith issued his Memorandum and Recommendation on May 11, 2007, recommending that Plaintiff’s experts be struck (Mem. at 3) and recommending that Plaintiff’s design, marketing and warranty claims be dismissed (Mem. at 7 & 9). For the reasons stated in its Motion for Summary Judgment and Reply

⁶ In this case, Dr. Labbe’ specifically negated causation by testifying that “any medical expenses or other related damages experienced by Mr. Kaye . . . flow from and were caused by his skiing accident” not the breakage of the plate which Dr. Labbe’ averred was defect-free. Labbe’ Aff. 8.

in Support, Synthes agrees with Judge Smith and makes no objection to these specific findings. Synthes reserves the right, under the Rules or in equity, to respond to any objection presented by Plaintiff to the matters which Judge Smith properly determined in the Memorandum and Recommendation.

IV.

Conclusion

By its motion for summary judgment, Defendant Synthes (U.S.A.) ("Synthes") demonstrated that there is no genuine issue of material fact and as a matter of law summary judgment should be granted in its favor. In its Reply in Support, Synthes demonstrates that Plaintiff Douglas Kaye fails to meet his burden of proof and burden of coming forward on his allegations of design defect, manufacturing defect and marketing defect. Synthes also demonstrates that there is no basis for Plaintiff's spoliation allegation and that this allegation does not meet the requirements stated by the United States 5th Circuit Court of Appeals in *King v. Ill. Central Railroad*, No 02-60587 (5th Cir. July 21, 2003).

For the foregoing reasons, Synthes (U.S.A.) objects to some of Magistrate Smith's conclusions, findings and recommendations set out in his Memorandum and Recommendations signed on May 11, 2006, and asks that the Court, after its *de novo* review, grant Synthes's motions to strike and for summary judgment in their entirety. Synthes (U.S.A.) further prays for all relief to which it may be entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

A true and correct copy of the above and foregoing pleading was duly served upon all parties or their counsel of record by messenger, facsimile, or by placing same in the United States Mail, postage prepaid, properly addressed to the counsel of record, on this the 25th day of May, 2007.

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